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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/026,517	12/27/2001	Pu Zhou	12013/61601	9382

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WASHINGTON, DC 20005

EXAMINER

SCHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 12/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/026,517	ZHOU, PU	
	<b>Examiner</b>	<b>Art Unit</b>	
	Laura C. Schell	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-9,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-9, 11 and 12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date: _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

Examiner acknowledges that claims 2, 10 and 28 have been canceled and that claims 13-27 have been withdrawn.

### ***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 11 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Wallace (US Patent No. 5,554,114). Wallace discloses a steerable guide catheter (Fig. 5) having an entrance and exit orifice, a first wall (14) surrounding a channel (16) linking the entrance and exit orifices, the first wall having a bendable curve memory portion (26 and 32, see col. 9, lines 1-4), wherein the curve memory portion is bent into a predetermined shape and contains a plurality of flushing orifices (18i) and where the steerable guide catheter contains a first layer (48, col. 7 line 67 through col. 8 line 11), a second layer (14) and a

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third layer (20), each layer having a different hardness. While Wallace does not disclose expressly that the three layers are of different hardness, it does disclose that the third layer (20) is made of a metal wire such as stainless steel (col. 8, lines 65-67) and the second layer (14) is made of materials well known in the art such as PTFE (col. 9, lines 17-24) which is inherently a softer material than metal. Wallace does not expressly disclose that the first layer (48) is of a different hardness, but it is inherent from the reference's specification that in order for the first layer (48) to keep the wire straight while within the first layer, the first layer must be of a harder material, otherwise the wire would revert to its coiled shape and the first layer would deform with it.

In reference to claim 12, Wallace does not disclose expressly that the inside surface of the catheter includes a lubricious treatment, but the practice is so well known in the art that it can be assumed to be included in the reference, otherwise the frictional force would be too great to overcome and the coiling of the catheter would ruin and distort the wall of the catheter.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany (US Patent No. 5,222,949) in view of Paskar (US Patent No. 6,623,449).

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Kaldany discloses the device substantially as claimed including a medical catheter system comprising: a first catheter (30) having an entrance orifice (Fig. 7a, end near 200), exit orifice (end near 204), a channel connecting the orifices (channel between 204 and 202), a wall surrounding the channel (Fig. 1a), the hardness of the wall, when considered from an initial reference point at the entrance orifice and traveling towards the exit orifice, regardless of the orientation of the wall, decreasing in hardness in a first distinct region (10) then increasing in hardness in a second distinct region (20) and then decreasing in hardness again in a third distinct region (10). As disclosed in Figures 5 and 6, the tube is made with a first softer region (10), then a harder region (20), and then a softer region (10), this is also described in column 3, lines 17-31. Kaldany, however, does not disclose expressly a second catheter located within the first catheter, or that the second catheter has a plurality of flushing orifices. Paskar, however, discloses a first catheter (33) with a second catheter located within the first catheter (35), the first catheter sized to allow the second catheter to move within it, and the second catheter having a steerable distal portion (col. 3, lines 6-25). Paskar further discloses that the second catheter (35) has a plurality of flushing orifices (Fig. 16a) capable of allowing fluid to pass from an outside surface of the second catheter to an inside surface of the second catheter. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Kaldany to include a second catheter within the catheter as taught by Paskar in order to provide an outer deformable catheter with a second catheter within it able to perform other tasks or procedures.

Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paskar (US Patent No. 6,623,449) in view of Kaldany (US Patent No. 5,222,949).

Paskar discloses the device substantially as claimed including a second inner catheter (35) with a curve memory portion (col. 6, lines 1-12), however Paskar does not expressly disclose the curve memory portion containing cross-linking polymer activated by ultraviolet light and becoming shaped. Kaldany, however, discloses a curve memory portion containing a cross-linking polymer that when activated by ultraviolet light will become shaped into a predetermined shape (col. 1, lines 34-60). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Paskar to include curve memory regions with ultraviolet light activated polymer regions on the second catheter, as taught by Kaldany, in order to provide the second catheter with a flexible structure that can later be hardened into necessary shapes and configurations for the stability of medical tasks and procedures to safely take place.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany in view of Paskar as applied to claim 1 above, and further in view of Fleming (US Patent No. 5,718,678). Kaldany in view of Paskar discloses the device substantially as claimed except for a third catheter within the second catheter, the third catheter able to move within the second catheter. Fleming, however, discloses a third catheter (12) within a second catheter (26), wherein the third inner catheter is able to move within the second catheter (col. 9, lines 25-32). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Kaldany in view of Paskar

with the third inner catheter as taught by Fleming, in order to provide yet another catheter to perform another task or procedure.

Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaldany in view of Paskar as applied to claim 1 above, and further in view of Berg et al. (US Patent No. 6,858,024). Kaldany in view of Paskar discloses the device substantially as claimed except for the second catheter containing an outer layer with a first hardness being softer than an inner layer with a second hardness. Berg, however, discloses a section of a catheter (Fig. 14, 61) containing an outer layer (18) with a first hardness and an inner layer (70) with a second hardness that is harder than the first hardness (col. 10, lines 44-50). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Kaldany in view of Paskar with the first layer of hardness and the second layer of hardness, as taught by Berg, in order to provide a catheter with a flexible but rigid structure.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent No. 6,295,990 to Lewis discloses a catheter with a second inner catheter that contains a plurality of flushing orifices capable of allowing fluid to pass from an outside surface of the second catheter to an inside surface of the second catheter.

### ***Response to Arguments***

Applicant's arguments filed 09/06/2005 have been fully considered but they are not persuasive. Applicant's argument that Wallace does not disclose a three layer catheter is not valid as presented above and in Figure 5, where Wallace discloses a

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steerable guide catheter with a first second and third layer. Wallace also discloses the different materials of which the three catheters are made, and each is of inherently different hardness. Finally, the examiner retracts the allowance of claims 1 and 3-8 as presented above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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